ALLERGAN

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FEB 2 0 2002

K014202

510(k) SUMMARY
TRADE NAME Multipurpose Solution

This summary uses the format provided in 21 CFR 807.92:

(a)(1) **Submitter:**

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Regulatory Affairs
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Summary Prepared: February 7, 2002

(a)(2) **Device Trade Name:** TRADE NAME Multi-Purpose Solution

Device Common Name: Soft (Hydrophilic) Contact Lens Solution

Device Classification Names: Accessories to Contact Lens Solution (86LPN)

(a)(3) **Identification of Predicate Device:** TRADE NAME Multipurpose Solution is substantially equivalent, in terms of disinfecting, cleaning, rinsing, storing and removing protein, to COMPLETE® brand Multi-Purpose Solution cleared for marketing under 510(k) K003252 and 510(k) K013479.

TRADE NAME Multipurpose Solution meets the guidelines set forth in FDA's May 1, 1997 Guidance for Industry; Premarket Notification 510(k) Guidance Document for Contact Lens Care Products.

(a)(4) **Device Description:** TRADE NAME Multipurpose Solution is a sterile, isotonic, buffered, aqueous solution containing sodium chloride, potassium chloride, phosphate buffer, edetate disodium, and Poloxamer 237 with polyhexamethylene biguanide 0.0001% as a preservative.

As with COMPLETE® brand Multi-Purpose Solution, this product is a clear, colorless solution, packaged in the same plastic bottles with controlled dropper tips.

(a)(5) **Intended Use (Indications for Use):** TRADE NAME Multi-Purpose Solution is indicated for the care of soft (hydrophilic) contact lenses. Use this product, as recommended by your eye care practitioner, to:

- Chemically (NOT HEAT) Disinfect
- Clean
- Rinse
- Store
- Remove Protein

These **Indications for Use** are the same as for COMPLETE® brand Multi-Purpose Solution except for the conditioning claim, which was deleted due to the removal of Hydroxypropyl methylcellulose (HPMC) from the formulation.

(a)(6) **Comparison of Technological Characteristics:** The formulation of TRADE NAME Multipurpose Solution is identical to the formulation of COMPLETE® brand Multi-Purpose Solution except it does not contain the lubricant, HPMC. Without this lubricant, the product loses its conditioning qualities, therefore this indication has been removed from the product labeling. There are no other differences in the technological characteristics of TRADE NAME Multipurpose Solution and the predicate device.

(b)(1) **Nonclinical Data:**

Solution Compatibility: We compared the compatibility of the alternate formulation with the predicate device, COMPLETE® brand Multi-Purpose Solution, using FDA Group I and IV soft contact lenses. Lens diameter, power and basecurve were measured before, during and after completion of 30 cycles. Also, lens clarity and visual appearance were observed and evaluated. The results for TRADE NAME Multipurpose Solution were comparable to or better than those for COMPLETE® brand Multi-Purpose Solution. Therefore, TRADE NAME Multipurpose Solution is compatible with all soft (hydrophilic) contact lenses.

Cleaning Studies: We compared the ability of TRADE NAME Multipurpose Solution to maintain clean soft (hydrophilic) contact lenses with COMPLETE® brand Multi-Purpose Solution. Group I and IV lenses were examined for surface deposits and general cleanliness over a 30-day/30-cycle period which included a soak in artificial tears. Results show that TRADE NAME Multipurpose Solution is comparable to the predicate device/regimen and is an effective cleaner for soft (hydrophilic) contact lenses.

We also compared the ability of the proposed and predicate device formulations and one competitive product to passively remove lysozyme protein adsorbed to contact lens surfaces and within the lens matrix. The results of the study show that the proposed formulation was comparable to the predicate device formulation and has significantly (2 times) better passive protein cleaning ability than the competitive product.

Microbiological Studies: Antimicrobial efficacy studies using the same methods submitted under 510(k) K003252 and 510(k) K013479 were conducted for TRADE NAME Multipurpose Solution. All results were satisfactory.

Toxicological Studies: We performed an *in-vitro* cytotoxicity study. The results show that the alternate formulation is not cytotoxic and is comparable to COMPLETE® brand Multi-Purpose Solution.

Additionally, we performed a 21-day rabbit study in which the ocular effects of hydrophilic contact lenses treated with TRADE NAME Multipurpose Solution were evaluated in regimens with and without weekly enzymatic cleaning. The predicate device/regimen was used as the control. No ocular toxicity was observed and there were no clinically significant regimen-related ocular toxicity findings associated with the modified disinfecting solution.

(b)(2) **Clinical Data:**

Our interpretation of the testing matrices in FDA's May 1, 1997 Premarket Notification [510(k)] Guidance Document for Contact Lens Care Products is that this minor change in formulation does not require clinical testing to show substantial equivalence.

All nonclinical data show that TRADE NAME Multipurpose Solution is comparable to COMPLETE® brand Multi-Purpose Solution for its indicated uses: disinfecting, cleaning, rinsing, storing and removing protein.

(b)(3) **Conclusions Drawn from Data Supporting Equivalence Determination:** We conclude that the safety, efficacy and acceptability of TRADE NAME Multi-Purpose Solution is substantially equivalent to COMPLETE® brand Multi-Purpose Solution for disinfecting, cleaning, rinsing, storing and removing protein from all soft (hydrophilic) contact lenses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 0 2002

Allergan, Inc.
C/O Paul J. Nowacki
Manager, Regulatory Affairs
2525 Dupont Drive
P.O. Box 19534
Irvine, CA 92623-9534

Re: K014202
Trade/Device Name: TRADE NAME Multi-Purpose Solution
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) contact lens care products
Regulatory Class: Class II
Product Code: LPN
Dated: December 20, 2001
Received: December 21, 2001

Dear Mr. Nowacki:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) NUMBER:
(IF KNOWN): K014202

DEVICE NAME: TRADE NAME Multi-Purpose Solution

INDICATIONS FOR USE:

TRADE NAME Multi-Purpose Solution is indicated for the care of soft (hydrophilic) contact lenses. Use this product, as recommended by your eye care practitioner, to:

- Chemically (NOT HEAT) Disinfect
- Clean
- Rinse
- Store
- Remove Protein

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter-Use ✓ JS
(Per 21 CFR 801.109 Kara Walsh) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K014202